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10/714,253	11/14/2003	Victor I. Sementchenko	3536.1	9685

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SANTA CLARA, CA 95051

EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,253

Applicant(s)

SEMENTCHENKO ET AL.

Examiner

Teresa E. Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to an amendment filed September 25, 2006. Claims 1-9 were previously pending. Applicants amended claim 1 and added new claims 10-12. Claims 1-12 are pending and will be examined.
2. Applicants' amendments overcame the following: rejection of claims 1-5 under 35 U.S.C. 102(a) as anticipated by Tamayo et al. as evidenced by Rava et al.; rejection of claims 1-5 under 35 U.S.C. 102(e) as anticipated by Tamayo et al. as evidenced by Rava et al.; rejection of claims 6-9 under 35 U.S.C. over Tamayo et al. as evidenced by Rava et al. and Lockhart et al.
3. Applicants' amendment to the specification obviated the objection presented in the previous office action.
4. This office action presents new grounds for rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5 and 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Shoemaker et al. (U.S. Patent No. 6,713,257 B2).

Regarding claim 1, Shoemaker et al. teach a method of transcriptional profiling comprising: subjecting a biological sample to an exogenous stimulation (Shoemaker et al. teach subjecting

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cells to external stimuli (col. 7, lines 48-51; col. 16, lines 61-67; col. 17, lines 1-17; col. 23, lines 52-67; col. 24, lines 1-14; col. 25, lines 6-10 and 22-40; col. 33, lines 25-67; Fig. 13).);

measuring transcriptional activity of the biological sample at a first differentiation stage

(Shoemaker et al. teach measuring transcriptional activity for at least first and second different conditions, therefore they inherently teach cells at two different differentiation stages (col. 7, lines 48-51; col. 16, lines 61-67; col. 17, lines 1-17; col. 23, lines 52-67; col. 24, lines 1-14; col. 25, lines 6-10 and 22-40; col. 33, lines 25-67; Fig. 13).);

measuring transcriptional activity of the biological sample at a second differentiation stage

(Shoemaker et al. teach measuring transcriptional activity for at least first and second different conditions, therefore they inherently teach cells at two different differentiation stages (col. 7, lines 48-51; col. 16, lines 61-67; col. 17, lines 1-17; col. 23, lines 52-67; col. 24, lines 1-14; col. 25, lines 6-10 and 22-40; col. 33, lines 25-67; Fig. 13).); and

comparing the transcriptional activities from the first and second differentiated stages in at least 5 Mbases, 50 Mbases or 100 Mbases of the genome to obtain a transcription profile, wherein such detection is conducted with probes targetting the 5 Mbases, 50 Mbases or 100 Mbases of the genome at a resolution of 100 bps or less (Shoemaker et al. teach comparing the transcriptional profile at the different conditions (Shoemaker et al. teach measuring transcriptional activity for at least first and second different conditions, therefore they inherently teach cells at two different differentiation stages (col. 7, lines 48-51; col. 16, lines 61-67; col. 17, lines 1-17; col. 23, lines 52-67; col. 24, lines 1-14; col. 25, lines 6-10 and 22-40; col. 33, lines 25-67; Fig. 13).). Shoemaker et al. teach profiling of the gene expression on chromosome 22 (col. 33, lines 25-32) and of the whole human genome (col. 36, lines 14-15), therefore they inherently teach detecting transcriptional activities of at least 5, 50 or 100 Mbases of the genome. Shoemaker et al. teach tiled arrays, where

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the probes span the entire region investigated and the resolution is determined by probe overlap (Fig. 1; col. 8, lines 10-40). They teach resolution of less than 100 bp (col. 11, lines 40-44).).

Regarding claim 2, Shoemaker et al. teach hybridizing RNA to the array (col. 15, lines 1-67; col. 16, lines 1-31).

Regarding claims 3-5, Shoemaker et al. teach at least 500,000 different probes on the array (col. 9, lines 60-67; col. 10, lines 1-5). Since a 1x3 inch slide has a surface of about 19 cm², with a probe density of 100,000 per cm², the total number of probes would be 1,900,000.

Regarding claims 10-12, Shoemaker et al. teach the resolution of 30 bps or less, 10 bp or less and a single base resolution (col. 11, lines 40-44; col. 12, lines 13-15).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shoemaker et al. (U.S. Patent No. 6,713,257 B2) and Lockhart et al. (U.S. Patent No. 6,040,138 A; cited in the previous office action).

A) Regarding claims 6 and 7, Shoemaker et al. teach high-density oligonucleotide arrays, but do not teach mismatch probes.

Regarding claim 8, Shoemaker et al. teach the cells being responsive to stimulation (Fig. 13; col. 33, lines 25-67; col. 34, lines 1-40).

Regarding claim 9, Shoemaker et al. teach tumor-derived cell lines (col. 33, lines 56-62).

B) Regarding claims 6 and 7, Lockhart et al. teach high density oligonucleotide arrays for transcriptional profiling (Abstract) which contain perfect match and mismatch probes, with a mismatch located in the center of the probe (col. 2, lines 35-55; col. 3, lines 30-38; col. 7, lines 21-34; col. 16, lines 62-67; col. 17, lines 1-27).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the mismatch probes of Lockhart et al. in the method of transcriptional profiling on arrays of Shoemaker et al. The motivation to do so, provided by Lockhart et al., would have been that the mismatch probes provided a control for non-specific binding and cross-hybridization and the difference in intensity between perfect match and mismatch probes provided a measure of hybridization material concentration (col. 17, lines 15-27).

9. No claims are allowed.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
11/16/06